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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/808,031	03/03/1997	SUMIKO INOUYE	377.5888P	5819

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HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/808,031	Applicant(s) INOUE ET AL.
	Examiner Richard G Hutson	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 January 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-8,12 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-8,12 and 15-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>46</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/13/2003 has been entered.

Applicants amendment of the specification and cancellation of claim 10, amendment of claims 1, 7, and 12 without prejudice is acknowledged. Claims 1, 2, 4-8, 10, 12 and 15-17 are still at issue and are present for examination.

Applicants' arguments filed on 1/13/2003, Paper No. 49, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicants traversal of the previous withdrawal of newly submitted claim 10 from consideration based on the requirement for restriction is acknowledged, however the issue is considered moot in light of applicants cancellation of claim 10.

Specification

The disclosure is objected to because of the following informalities: Previously it was pointed out to applicants that on page 11, lines 17-22, the specification recites "Xiong and Eickbush (1990)", "Hsu et al. 1992b", "Sun et al. 1991" and "Herzer et al. 1992", yet these references are not listed with the other references in the specification so it is unclear as to the exact citation upon which applicants are referring. In response to this objection applicants have amended the specification to include the journal title for "Xiong and Eickbush (1990)", and "Hsu et al. 1992b", "Sun et al. 1991" and "Herzer et al. 1992". Applicants amendment of the previous reference "Sun et al. 1991" has **deleted the year of the reference publication.**

Further as previously stated and acknowledged by applicants, the recitation "Hsu et al. J. Bact., 174 (7): 2384-2387, April 1992b" is confusing with regard to "1992b".

Applicants had previously amended the above passage to include Sequence information (i.e. SEQ ID NOs 32-38, See amendment G, Paper No. 29), however the above referred to amendment at page 11, lines 17-22, has now deleted the reference to the sequences in the drawing. These SEQ ID NO's should be re-inserted.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities:

Newly amended claim 1 recites "(SEQ ID. 1)". It is believed that this should be "(SEQ ID No:1)".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 6, 12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (claims , 2, 4, 5, 6, 12 and 17 dependent on) is indefinite in that the recitation "of (SEQ ID. 1), or a substantially homologous amino acid sequence..." is unclear for a number of reasons. First, the use of the parenthesis surrounding SEQ ID. 1 are unclear given the context of the claim in which they are used and it is suggested that they be deleted. Second, SEQ ID NO: 1 is a nucleic acid sequence, not an amino acid sequence. The recitation is interpreted for the purpose of advancing prosecution as "encoded by SEQ ID NO: 1, or a substantially homologous amino acid sequence....". Thirdly, the instant claims are indefinite in the recitation of "substantially homologous " as this phrase is unclear absent a statement as to what applicants constitute "substantially homologous ". As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO:1, a sequence must be to be included within the scope of these claims.

Claim 6 is indefinite in the recitation "wherein the sequence..." as claim 6 is drawn to the bacterial RT of claim 1 and claim 1 refers to three different "sequences". It is unclear to which "sequence" this recitation in claim 6 refers.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 12, 15, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it applied to previous claims 1, 2, 4-6, 12, 15, 16 and 17. In response applicants have amended claims 1 and 12 and continue to traverse this rejection as it applies to the now amended claims.

Applicants traverse this rejection on the basis that claim 1 has now been amended "to claim the reverse transcriptase of (SEQ ID NO: 1 or a substantially homologous amino acid sequence)" and the claims thus provide adequate structural description of reverse transcriptase. As discussed above under 112 second paragraph rejection, applicants newly added recitation that is a part of applicants "adequate structural description" of the claimed genus of reverse transcriptases is unclear and thus

this newly added recitation does not help applicants structural description of the claimed genus.

Applicants further submit that claim 15 provides more than a mere recitation of a 4- or 5- amino acid motif, but rather claim 15 requires that the claimed reverse transcriptases must have a YXDD box along with an amino acid sequence "Asn-Xaa₁-Asn-Xaa₂", wherein Xaa₁-Xaa₂ are hydrophobic residues and that given the specificity of interaction between hydrophobic residues along with the particular interaction of triocine 1 aspiratic acid, one skilled in the art would recognize applicants were in possession of the claimed genus of Claims 15 and 16. It is noted that applicants argument which is based on the motif "Asn-Xaa₁-Asn-Xaa₂" should in actuality be based on the motifs "Asn-Xaa₁" or "Asn-Xaa₂". Regardless, this argument is not persuasive, as previously stated, the mere recitation of a four or five amino acid motif or even a number of number of such motifs conserved among a number of bacterial reverse transcriptases that are themselves hundreds of amino acids in length is not an adequate structural description. Applicants claim 15 and 16 are drawn to the genus of bacterial reverse transcriptases which comprise a YXDD and an Asn-Xaa₁-Xaa₂ motif. As the taught species of this genus are hundreds of amino acids in length, the genus of bacterial reverse transcriptases whose only structural limitation is a four and three amino acid motif is not adequately described with respect to the structure/function of the claimed genus. Applicants comments regarding the claim of an amino acid sequence with seven specific amino acid residues are unclear, however as much as applicants believe that an additional seven amino acid residues would further describe the claimed

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genus, this is not found persuasive for the same reasons discussed above that a four or five amino acid motif or multiple amino acid motifs do not adequately describe the claimed genus of bacterial reverse transcriptases.

Given this lack of an adequate structure to function/activity relationship of the disclosed RT species, the skilled artisan would not recognize applicants were in possession of the claimed genus.

Claims 1, 2, 4, 5, 6, 12 and 17 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, because applicants amendment of claim 1, reciting "of (SEQ ID. 1), or a substantially homologous amino acid sequence..." is not supported by the original disclosure and is considered new matter.. While applicants in their previous response, Paper No. 49, 1/13/2003, have pointed out where they believe they have support for such an amendment, such support was not found. It is acknowledged that applicants do have support for the bacterial reverse transcriptase of SEQ ID NO: 1, however not for those bacterial reverse transcriptases having a substantially homologous amino acid sequence".

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 10, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim and Mass (Cell 56:891-904, 1989).

The rejection is stated in the previous office actions.

Applicants have amended claims 1 (See above discussion regarding 112 first and second paragraph rejections) and 7 in response to this rejection and traverse the rejection as it applies to the newly amended claims.

Applicants submit that the reference Lim and Mas fail to teach or suggest the presence of a 485 amino acid open reading frame, which is now recited in claim 1, but rather Lim and Mas disclose an open reading frame that is 325 amino acids in length.

Applicants argument is not persuasive because newly amended claim 1 does not recite that the claimed bacterial reverse transcriptase must be encoded by a 485 amino acid open reading frame, but rather the claimed bacterial reverse transcriptase is merely described as being a substantially homologous amino acid sequence of SEQ ID NO: 1 (SEQ ID NO: 2) (See above 112 second paragraph rejection) and as applicants have not defined a substantially homologous amino acid sequence, the bacterial reverse transcriptase taught by Lim and Mas is considered to be encompassed by those

bacterial reverse transcriptases having a substantially homologous amino acid sequence as SEQ ID NO: 2(that sequence which is encoded by SEQ ID NO: 1).

In response to applicants arguments regarding whether the bacterial reverse transcriptase taught by Lim and Mas comprises a Asn-Xaa1-Xaa2 sequence, applicants attention is drawn to that sequence which is encoded by approximately nucleotide positions 512-520, (See figure 9, page 896) which is Asn-Phe-Ile, which satisfies the earlier referred to inherent limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-8 and 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over either of Inouye et al. (US Pat. 5,320,958 or US Pat. 5,434,070), in view of the combination of Rice et al. (July 1993), Xiong et al. (1990) and Hsu et al. (Apr. 1992).

The rejection is stated in the previous office actions.

Applicants have amended claims 1 (See above discussion regarding 112 first and second paragraph rejections) and 7 in response to this rejection and traverse the rejection as it applies to the newly amended claims.

Applicants submit that the combination of the above references is a result of hindsight construction that uses an "obvious to try" standard.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In support of applicants obvious to try argument, applicants submit that Rice et al. refer to the highly diverse nature of msDNA producing retroelements in rhizobial strains and that this highly diverse nature makes isolation and purification of these retroelements difficult and unpredictable. Applicants submit that given the mobility, small percentage of strains of bacteria containing retrons, diverse nature of retron elements among strains, lack of ordinary cross hybridization and diverse behavior of retrons, the isolation and purification of reverse transcriptases only obvious to try. This argument is not found persuasive, because as previously stated the references not only describe which specific organisms and genera of organisms contain the reverse transcriptases, but detail screening methods for the further detection of such in other species. Further applicants arguments regarding the mobility of retroelements is

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unclear as how this applies to the expectation of success in isolating bacterial reverse transcriptases of the claimed genus.

Claims 1, 2, 4-6, 8, 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (Journal of Bacteriology 174(7): 2384-2387, April 1992), as applied to claims 1, 2, 4-8 and 15-17 above, and further in view of Lim and Mass (Cell 56:891-904, 1989).

The rejection is stated in the previous office actions.

Applicants have amended claims 1 (See above discussion regarding 112 first and second paragraph rejections) and 7 in response to this rejection and traverse the rejection as it applies to the newly amended claims.

Applicants submit that contrary to the assertion by the examiner in the previous office action, the introduction of Hsu et al. does not discuss the homologies of msDNA from "mZantas" and *E. coli*, but rather Hsu et al. discusses the similarity between mZantas and Auranticaca. It is admitted that while the referred to passage of Hsu et al. may not teach homologies between *M. xanthus* and *E. coli*, they do teach the existence of msDNAs in both *M. xanthus* and *E. coli*, and this supports the motivation to combine these references.

Remarks

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
March 21, 2003